Fatigue Testing of Siltex Moderate Profile Gel Mammary Using the Cyclic Crease Fold Apparatus

Report Originated By:

Signature of Originator	Date
David Derrick, Lab Manager, QA	
Printed Name, Title, Department	

Report Approved By:

Signature	Date
Printed Name, Title, Department	
Signature	Date
Printed Name, Title, Department	

1.0 PURPOSE

This report documents the preliminary test results of in-vitro cyclic fatigue testing of Siltex Round Moderate Profile Mammary Implants. Fatigue testing using the Cyclic Crease Fold Apparatus (CCF), results in a failure that is similar in size and structure to those see in explanted devices.

2.0 BACKGROUND

Mammary prostheses experience various forms of mechanical stresses during their in-vivo life. These stresses are both compressive and cyclic. Normal everyday movements like walking, running, flexing, and bending cause these stresses, which result in the shell of the prosthesis to a fatigue lifetime. Mentor has actively studied the fatigue life of mammary implant by conduction fatigue or cyclic compression testing between flat plates at several load amplitudes. This methodology produces a cycles to failure load dependent plot which is used to calculate lifetime prediction of the mammary prosthesis.

The FDA has implied that the current test methodology of fatigue testing, i.e. flat plates is not predictive of clinical failures. The FDA recommended that mammary implant manufactures perform fatigue testing that mimics expected in-vivo conditions.

To address FDA recommendation, Mentor began with the examination of explanted gel mammary returned to the Product Evaluation Department (PE) for evaluation. Mentor Corporation conducted an investigation into the modes of failures of gel devices returned to Mentor PE department as a domestic U.S. complaint, Barber [1]. This study indicated that of the domestic complaints classified as "Rent-Unknown Cause", 14% of the actual failures were attributed to shell fatigue. This type of failure results from folding (creasing) of the shell. This failure mechanism was initially identified in Siltex Saline devices as a crease fold or fold flaw failure with evidence of Siltex cracking Ref, "Siltex Saline Cracking Analysis", Philip Yang, V.P. Technical Studies and Submissions.

In cases of crease fold failures in Siltex saline devices, the leak usually occurs at the tip of the crease. It is hypothesized that the failure is initiated in the Siltex layer where there are stress concentrations due to texturing. Under stress and continuous motion of the crease tip the Siltex layer separates or cracks and with time theses cracks cause a rent in the shell. This failure is further characterized by a surface indentations or ridges on the inside surface of the shell that extend from the point of failure along the creased area forming a plume/feathering appearance when examined under a microscope. These same failure characteristics can be seen in explanted Siltex gel devices as described in the Barber report [1]. Additional studies Brandon, et al [2] substantiated this failure mechanism in gel devices in which shell rents were identified as a fold flaw/fatigue failures.

3.0 TEST DESCRIPTION

The main target of previous laboratory efforts has been to simulate crease fold failure of Siltex saline devices in-vitro. We have been able to design equipment and develop a test method that produce Siltex crease fold failures in saline devices that imitate the in-vivo crease fold failures seen in returned Siltex saline device. The objective in using this equipment and test method is to evaluate whether, under similar test conditions, fatigue failures that imitate the in-vivo crease fold failures seen in returned Siltex gel devices can be repeatable produced.

In order to explicate test fixture variation two (2) test apparati, each accommodating four (4) devices will be used. Each test apparatus is divided into two (2) boxes with each box divided into two (2) smaller boxes that hold the test devices (Fig #1). Due to the size restraints of the test apparatus, the maximum volume size of the test devices will be restricted to 325cc.

3.1 Eight (8) devices were placed into the two (2) test apparati. Each sample device along with the corresponding test apparatus foot was adjusted achieve a smooth, shallow crease. In order to minimize test variation, the position of each foot was duplicated as close as possible on each sample device.

3.2 Using RTV adhesive, the test apparatus foot was adhered to the anterior aspect of each sample device and the radius and posterior aspect of each sample device was adhered to the sides and bottom of the test apparatus. The RTV adhesive was cured for 24 hours before any additional adjustments were made.

3.3 The air pressure was adjusted to a minimum PSI to achieve a smooth well-defined crease along the anterior aspect of the sample device.

3.4 Each section of the test apparatus was filled with a normal saline solution.

4.7 The stroke of the test apparatus was adjusted to 1/2 of an inch, the counter is reset to zero.

4.8 The motor was turn on and the speed control adjusted on each of the test apparatus to achieve a 60 stroke per minute frequency.

4.10 Once a day, all sample devices were visually inspected for signs of failure.

4.0 RESULTS

The date, none of the test samples has failed. All eight (8) devices have endured over 12M cycles with no visible signs of fatigue stress. The number of test cycles without a failure is not unexpected based on the analysis performed by Dr Barber [1]. This analysis reinforces the hypothesized mechanism of this type of failure; shell fatigue. A fatigue failure takes time to develop. In the analysis, no fatigue failures were observed in gel devices implanted less that one (1) year and only one (1) device per year failed in years 2 and 3 post implant. The explant population with fatigue failure had an estimated mean life of 4 to 6 years in-vivo. Assuming five (5) hours of walking per day at one-step per second as the dominate source of the cyclic motion of a device in-vivo. This yields a figure of 540,000 cycles per month or 6.4M per year. The number of cycles to date on the test devices would be equivalent to two (2) years in-vivo.

Because no failure was observed in the test samples, no conclusions can be made. All test samples will be fatigue cycled till failure at which point the cycles to failure will be analyzed and used for a comparison to PE data.

5.0 REFERENCES

1 Barber J.R., "An Investigation of The Modes of Failure of Devices In The Rent-Unknown Cause Category of The Product Evaluation Database"

2 Brandon H.J., Savoy T.L, Wolf C.J., Jerina K.L., "Analysis of In-Vivo Failure Mechanisms of Mentor Silicone Gel Breast Implants".

FIG #1